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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,299	WOOD ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 7-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6 and 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/02, 6/1/04, 9/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants should note that the examiner for this case has changed.

Response to Amendments

Applicant's amendments filed 6/26/06 to claim 5 have been entered. Claims 14-28 have been added. Claims 1-28 remain pending in the current application.

Election/Restrictions

Applicant's election with traverse of Group II, claims 5 and 6 (and new claims 14-28, which depend variously from claim 5), in the reply filed on 6/28/06 is acknowledged. The traversal is on the ground(s) that the composition of claim 5 is "literally prepared according to the method of claim 1 and thus cannot be made by another or materially different process" (Reply, page 10, paragraph 1). Applicants further allege that searching both inventions would not require an additional search or burden on the Office (*ibid.*). These arguments have been fully considered, but they are not persuasive.

Claim 5 as amended is a product-by-process claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Claim 5 is drawn to a composition comprising cells, said composition being free of large cellular

conglomerates. Applicant has provided no evidence that the process steps of claim 5 would make a different product than, for example, growing cells using standard cell culture methods. The composition of Group II **as claimed** merely comprises single cells or "small" aggregates thereof. The other steps recited in claim 5 do not clearly impart any particular physical or structural attributes to the elected **composition.** Therefore, searching the method steps of Group I would indeed require additional search, since these steps are not material to the patentability of the composition of Group II (see art rejections, below).

Applicants allege that searching both distinct inventions would not burden the Office. In fact, burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4 and 7-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/28/06. Examination on the merits will commence on claims 5, 6, and 14-28 ONLY.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Step (a) of claim 5 require subjecting a tissue sample to a dissociating means "**capable of** dissociating cellular stratum in the tissue sample," but the claim does not actually require a step in which said sample is dissociated. Clarification is required. The examiner suggests the claim be amended to require subjecting a tissue sample to a dissociating means "that dissociates cellular stratum" such that a dissociation step is required.

Similarly, step (b) of claim 5 refers to a nutrient solution "capable of maintaining the viability of the cells," which does not require that viability actually be maintained. Clarification is required.

Step (c) of claim 5 recites, "the cellular suspension produced according to step (b)," but it is not clear that step (b) yields a suspension of cells. Furthermore, it is not clear whether "cellular suspension" refers to "a suspension of whole cells in a liquid" or to "a suspension made from cells, but not necessarily comprising whole cells." Clarification is required.

Step (b) of claim 5 refers to "xenogenic serum," but no point of reference is provided for the relative term "xenogenic." Clarification is required.

Step (c) of claim 5 also refers to "large cellular conglomerates," but no point of reference is provided for the relative term "large." Clarification is required.

Because claims 6 and 14-26 depend from indefinite claim 5 and do not clarify all of these points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 6 requires that the composition of claim 5 be prepared from "autologous cells," but no point of reference is provided for the relative term "autologous." Clarification is required.

Claim 22 refers to "a tissue biopsy derived from skin," but it is not clear how closely related to skin said biopsy must be. The term "derived from" merely requires some degree of similarity or a relationship through some unknown process. Clarification is required. The examiner suggests "derived" be replaced with "isolated."

Step (a) of claim 27 requires subjecting a tissue sample to an enzyme solution "**capable of** dissociating cellular stratum in the tissue sample," but the claim does not actually require a step in which said sample is dissociated. Clarification is required. The examiner suggests the claim be amended to require subjecting a tissue sample to a solution "that dissociates cellular stratum" such that a dissociation step is required.

Similarly, step (b) of claim 27 refers to a nutrient solution "capable of maintaining the viability of the cells," which does not require that viability actually be maintained. Clarification is required.

Step (b) of claim 27 refers to "xenogenic serum," but no point of reference is provided for the relative term "xenogenic." Clarification is required.

Step (c) of claim 27 recites, "the cellular suspension produced according to step (b)," but it is not clear that step (b) yields a suspension of cells. Furthermore, it is not

clear whether "cellular suspension" refers to "a suspension of whole cells in a liquid" or to "a suspension made from cells, but not necessarily comprising whole cells." Clarification is required.

Step (a) of claim 28 requires subjecting a tissue sample to an enzyme solution "**capable of** dissociating cellular stratum in the tissue sample," but the claim does not actually require a step in which said sample is dissociated. Clarification is required. The examiner suggests the claim be amended to require subjecting a tissue sample to a solution "that dissociates cellular stratum" such that a dissociation step is required.

Similarly, step (b) of claim 28 refers to a nutrient solution "capable of maintaining the viability of the cells," which does not require that viability actually be maintained. Clarification is required.

Step (b) of claim 28 refers to "xenogenic serum," but no point of reference is provided for the relative term "xenogenic." Clarification is required.

Step (c) of claim 28 recites, "the cellular suspension produced according to step (b)," but it is not clear that step (b) yields a suspension of cells. Furthermore, it is not clear whether "cellular suspension" refers to "a suspension of whole cells in a liquid" or to "a suspension made from cells, but not necessarily comprising whole cells." Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5, 6, and 14-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Yannas et al. (1983, U.S. Patent 4,418,691; reference A). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline.

Yannas et al. teach a composition comprising cells dissociated from skin (column 4, lines 58-60), said cells suspended in physiological saline (column 5, lines 3-6), and said cells separated from each other (column 4, line 66, through column 5, line 1).

Claim 5 is a product-by-process claim; claims 6 and 14-24 depend from said claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In

this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, and 14-21 produce a composition that is materially and patentably distinct from the skin cell suspension of Yannas et al.

It is noted that applicant has employed "means" language in claims 5 ("physical or chemical dissociation means") and 14 ("chemical dissociating means"), for example. Applicant is advised that the specification does not provide a corresponding structure; therefore, in accordance with M.P.E.P. § 2182, the "means plus function" limitations in these claims have been interpreted broadly, *i.e.* with no structural limits.

Claims 5, 6, 14-21, and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (1990, EP 0 350 887; reference C2 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Suzuki et al. teach a composition comprising cells dissociated from heart tissue (Reference Example 1; page 4, lines 50-54), said composition lacking aggregates removed by a No. 100 (150μm) filter (page 4, line 55); and a physiological saline, specifically HEPES buffer (page 4, lines 52-56). The 150μm filter of Suzuki et al. is a size of "about 200μm," since the scope of "about" is not limited by the specification.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Suzuki et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirobe (1992, *Journal of Cellular Physiology* 152: 337-345; reference C3 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Hirobe teaches a composition comprising cells dissociated from mouse skin tissue (page 337, column 2, paragraph 3), said composition lacking aggregates removed by a 200μm filter ("single cell suspensions," *ibid.*); and a physiological saline, specifically melanoblast defined medium, which comprises salts (page 338, column 1, paragraph 2).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Hirobe. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Noel-Hudson et al. (1993, *In Vitro Cell and Developmental Biology – Animal* 31: 508-515; reference C6 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Noel-Hudson et al. teach a composition comprising cells dissociated from human foreskin tissue (page 509, column 1, paragraph 7), said composition lacking all aggregates removed by a 200μm filter ("individual cells;" *ibid.*); and a physiological saline, specifically Hanks' solution with calcium salts (*ibid.*).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In

this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Noel-Hudson et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, 14-21, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunawardana et al. (1994, U.S. Patent 5,352,806; reference B). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the nutrient media is a saline, possibly physiological saline.

Gunawardana et al. teach a composition comprising dissociated cells (column 22, line 64, through column 23, line 7), said cells separated from each other (column 23, lines 7-8). The cells in the composition of Gunawardana et al. are suspended in "medium containing fetal calf serum," which is physiological in the respect that cells grow therein and is a saline solution to the extent that it contains salt.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, and 14-21 produce a composition that is

materially and patentably distinct from the skin cell suspension of Gunawardana et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas et al. (1994, U.S. Patent 5,328,695; reference C). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Lucas et al. teach a composition comprising cells dissociated from muscle and skin tissue (Example 5; column 11, lines 11-25), said composition lacking aggregates removed by a 20μm filter (column 11, lines 25-28); and a physiological saline, specifically Tyrode's TM buffer (column 11, lines 10 and 29-30). The 20μm filter of Lucas et al. is a size of "about 50μm" or "about 75μm," since the scope of "about" is not limited by the specification; furthermore, a smaller filter would remove the same aggregates as a larger one, so the composition if Lucas et al. is identical to that in claims 25-28.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that

the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Lucas et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lavker et al. (1996, U.S. Patent 5,556,783; reference D). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Lavker et al. teach a composition comprising cells dissociated from skin tissue (Example 5; column 8, lines 43-50), said composition lacking aggregates removed by a 200μm filter (column 8, lines 52-54); and a physiological saline, specifically phosphate buffered saline (column 8, line 51). The 200μm filter of Lavker et al. is a size of "about 150μm," since the scope of "about" is not limited by the specification.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is

materially and patentably distinct from the skin cell suspension and muscle cell suspension of Lavker et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al. (1998, U.S. Patent 5,786,207; on 9/28/05 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells.

Katz et al. teach a composition comprising cells dissociated from tissue (Abstract; column 14, lines 63-64).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Katz et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne et al. (1999, *Biomaterials* 20: 283-290; reference C4 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Osborne et al. teach a composition comprising cells dissociated from human foreskin tissue (page 284, column 2, section 2.3), said composition lacking all aggregates removed by a 200μm filter ("single cell suspension;" *ibid.*); and a physiological saline, specifically serum-free keratinocyte medium (which comprises salts) (*ibid.*).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Osborne et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Dennis et al. (2001, U.S. Patent 6,207,451; reference E). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Dennis et al. teach a composition comprising cells dissociated from muscle tissue from which skin has been removed (column 12, lines 13-17), said composition lacking aggregates removed by 15 minutes of centrifugation at 1200xg (column 12, lines 20-21); and physiological salines, specifically calcium-free phosphate-buffered saline (column 6, lines 15-16); D&C solution, which comprises salts (column 5, lines 19-22, and column 6, lines 17-25); and F12 nutrient medium, which comprises salts (column 5, lines 14-17, and column 6, lines 24-26). The centrifugation step of Dennis et al. removes cell aggregates, as would the instantly claimed filters. The muscle tissue of Dennis et al. is "derived from skin" in that the neonatal rats (column 6, lines 10-15) comprise muscle and skin, and the muscle tissue is removed from these neonatal rats, *i.e.* derived from skin.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is

materially and patentably distinct from the skin cell suspension and muscle cell suspension of Dennis et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Claims 5, 6, and 14-28 are also rejected under 35 U.S.C. 102(a) as being anticipated by Dennis et al. (2001, U.S. Patent 6,207,451) for the reasons stated above

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

leb